



CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail to:
Box Missing Parts, Commissioner for Patents, Washington, DC 20231
on 26 JAN 2002

Julie M. Balot
Julie M. Balot

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | |
|---|---|
| In re application of: Michael G. Kahn et al. | Attorney Docket No.: FSTK 1004-1US |
| Application No.: 09/974,781 | Examiner: Unknown |
| Confirmation No.: 8124 | Group: 2166 |
| Filed: October 10, 2001 | ATTN: Initial Patent Examination Division |
| Title: CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY | |

SUBMISSION OF SUBSTITUTE DRAWINGS UNDER 37 CFR 1.84

BOX MISSING PARTS
Commissioner for Patents
Washington, DC 20231

Sir:

Pursuant to the enclosed Notice to File Missing parts of Nonprovisional Application dated October 26, 2001, applicants hereby submit forty-one (41) sheets of substitute drawings.

Respectfully submitted,

Date: 11/28/2002

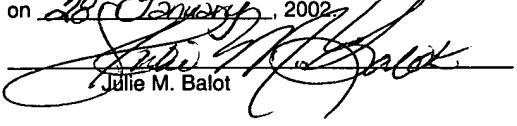
Warren S. Wolfeld
Warren S. Wolfeld, Reg. No. 31,454

HAYNES BEFFEL & WOLFELD LLP
P.O. Box 366
Half Moon Bay, California 94019
Phone: 650-712-0340
Fax: 650-712-0263



CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail to: Box Missing Parts, Commissioner for Patents, Washington, DC 20231 on 28 January, 2002.


Julie M. Balot

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re application of: Michael G. Kahn et al. | Attorney Docket No.: FSTK 1004-1US |
| Application No.: 09/974,781 | Examiner: Unknown |
| Confirmation No.: 8124 | Group: 2166 |
| Filed: October 10, 2001 | |
| Title: CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY | |

RESPONSE TO NOTICE OF MISSING PARTS OF APPLICATION

BOX MISSING PARTS
Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Notice to File Missing Parts of Application dated May 16, 2001, enclosed please find:

- [X] Form PTO-1533 (copy of Notice to be returned with response);
- [X] Three Declarations for Utility Patent Application signed by inventors;
- [X] Three Assignments signed by Inventor with Form PTO-1595;
- [X] Three Power of Attorney or Authorization of Agent forms signed by inventors;
- [X] A Power of Attorney or Authorization of Agent forms signed by Michael G. Kahn in his capacity as Vice President of FastTrack Systems, Inc.;
- [X] Statement Under 37 CFR 3.37(b) with copies of executed Assignments;
- [X] Submission of Substitute Drawings Under 37 CFR 1.84 along with 41 sheets of substitute drawings;
- [X] Preliminary Amendment;
- [X] Information Disclosure Statement;
- [X] Two pages of Form 1449 and copies of twelve (12) citations.;
- [X] Supplemental Application Data Sheet;
- [X] Petition for Extension of Time (one month);
- [X] Fee Transmittal for FY 2002; and
- [X] Check No. 1620 in the amount of \$893.00.

20230-TE247650

The Commissioner is hereby authorized to charge any additional fees that may be required and to credit any overpayment, to Deposit Account No. 50-0869 (Docket No. FSTK 1004-1US). A duplicate of this paper is enclosed.

Respectfully submitted,

Date: 1/28/2002

HAYNES BEFFEL & WOLFELD LLP
P.O. Box 366
Half Moon Bay, California 94019
Phone: 650-712-0340
Fax: 650-712-0263

Warren S. Wolfeld
Warren S. Wolfeld, Reg. No. 31,454

2017 RELEASE UNDER E.O. 14176



Sect 1

HH

Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2002

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT (\$ 893.00)

Complete if Known

| | |
|----------------------|-----------------|
| Application Number | 09/974,781 |
| Filing Date | 10/10/2001 |
| First Named Inventor | Michael G. Kahn |
| Examiner Name | Unknown |
| Group Art Unit | 2166 |
| Attorney Docket No. | FSTK 1004-1US |

METHOD OF PAYMENT

1. The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number **50-0869**

Deposit Account Name **Haynes Beffel & Wolfeld LLP**

Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

Applicant claims small entity status. See 37 CFR 1.27

2. Payment Enclosed:

Check Credit card Money Order Other

FEE CALCULATION (continued)

3. ADDITIONAL FEES

| Fee Code | Large Entity Fee (\$) | Small Entity Fee Code (\$) | Fee Description | Fee Paid |
|-----------------------------------|-----------------------|----------------------------|---|--------------------------|
| 105 | 130 | 205 | 65 Surcharge - late filing fee or oath | 65.00 |
| 127 | 50 | 227 | 25 Surcharge - late provisional filing fee or cover sheet | |
| 139 | 130 | 139 | 130 Non-English specification | |
| 147 | 2,520 | 147 | 2,520 For filing a request for ex parte reexamination | |
| 112 | 920* | 112 | 920* Requesting publication of SIR prior to Examiner action | |
| 113 | 1,840* | 113 | 1,840* Requesting publication of SIR after Examiner action | |
| 115 | 110 | 215 | 55 Extension for reply within first month | 55.00 |
| 116 | 400 | 216 | 200 Extension for reply within second month | |
| 117 | 920 | 217 | 460 Extension for reply within third month | |
| 118 | 1,440 | 218 | 720 Extension for reply within fourth month | |
| 128 | 1,960 | 228 | 980 Extension for reply within fifth month | |
| 119 | 320 | 219 | 160 Notice of Appeal | |
| 120 | 320 | 220 | 160 Filing a brief in support of an appeal | |
| 121 | 280 | 221 | 140 Request for oral hearing | |
| 138 | 1,510 | 138 | 1,510 Petition to institute a public use proceeding | |
| 140 | 110 | 240 | 55 Petition to revive - unavoidable | |
| 141 | 1,280 | 241 | 640 Petition to revive - unintentional | |
| 142 | 1,280 | 242 | 640 Utility issue fee (or reissue) | |
| 143 | 460 | 243 | 230 Design issue fee | |
| 144 | 620 | 244 | 310 Plant issue fee | |
| 122 | 130 | 122 | 130 Petitions to the Commissioner | |
| 123 | 50 | 123 | 50 Processing fee under 37 CFR 1.17(q) | |
| 126 | 180 | 126 | 180 Submission of Information Disclosure Stmt | |
| 581 | 40 | 581 | 40 Recording each patent assignment per property (times number of properties) | 40.00 |
| 146 | 740 | 246 | 370 Filing a submission after final rejection (37 CFR § 1.129(a)) | |
| 149 | 740 | 249 | 370 For each additional invention to be examined (37 CFR § 1.129(b)) | |
| 179 | 740 | 279 | 370 Request for Continued Examination (RCE) | |
| 169 | 900 | 169 | 900 Request for expedited examination of a design application | |
| Other fee (specify) _____ | | | | |
| *Reduced by Basic Filing Fee Paid | | | | SUBTOTAL (3) (\$ 160.00) |

2. EXTRA CLAIM FEES

| Total Claims | Extra Claims | Fee from below | Fee Paid |
|--------------|--------------|----------------|----------|
| 51 | -20** = 31 | x 9.00 | = 279.00 |
| 5 | -3** = 2 | x 42.00 | = 84.00 |
| | | | = |

Large Entity Small Entity

| Fee Code (\$) | Large Entity Fee (\$) | Small Entity Fee Code (\$) | Fee Description |
|---------------|-----------------------|----------------------------|--|
| 103 | 18 | 203 | 9 Claims in excess of 20 |
| 102 | 84 | 202 | 42 Independent claims in excess of 3 |
| 104 | 280 | 204 | 140 Multiple dependent claim, if not paid |
| 109 | 84 | 209 | 42 ** Reissue independent claims over original patent |
| 110 | 18 | 210 | 9 ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) (\$ 363.00)

**or number previously paid, if greater; For Reissues, see above

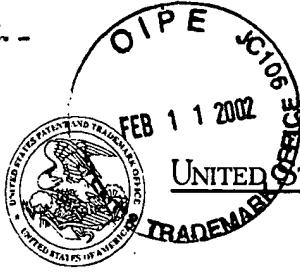
*Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$ 160.00)

SUBMITTED BY

| | | | | | |
|-------------------|--------------------------|--------------------------------------|--------|-----------|----------------|
| Name (Print/Type) | Warren S. Wolfeld | Registration No. (Attorney/Agent) | 31,454 | Telephone | (650) 712-0340 |
| Signature | <i>Warren S. Wolfeld</i> | | | Date | 1/28/2002 |

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

| APPLICATION NUMBER | FILING/RECEIPT DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NUMBER |
|--------------------|---------------------|-----------------------|------------------------|
| 09/974,781 | 10/10/2001 | Michael G. Kahn | FSTK 1004-1 |

22470
HAYNES BEFFEL & WOLFELD LLP
P O BOX 366
HALF MOON BAY, CA 94019

CONFIRMATION NO. 8124

FORMALITIES LETTER



OC00000006981383

Date Mailed: 10/26/2001

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
Applicant must submit \$ 370 to complete the basic filing fee for a small entity.
- Total additional claim fee(s) for this application is \$363.
 - \$279 for 31 total claims over 20.
 - \$84 for 2 independent claims over 3 .
- The oath or declaration is missing.
A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(l) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.
- **The balance due by applicant is \$ 798.**

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Substitute drawings in compliance with 37 CFR 1.84 because:
 - drawing sheets do not have the appropriate margin(s) (see 37 CFR 1.84(g)). Each sheet must include a top margin of at least 2.5 cm. (1 inch), a left side margin of at least 2.5 cm. (1 inch), a right side margin of at least 1.5 cm. (5/8 inch), and a bottom margin of at least 1.0 cm. (3/8 inch);

02/14/2002 BNNGUYEN1 00000017 09974781

| | |
|-----------|-----------|
| 01 FC:201 | 370.00 OP |
| 02 FC:203 | 279.00 OP |
| 03 FC:202 | 84.00 OP |
| 04 FC:205 | 65.00 OP |

*A copy of this notice **MUST** be returned with the reply.*

Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

2010 RELEASE UNDER E.O. 14176